BC CANCER
Provincial Health Services Authority

Participant Information and Consent Form

SUPR-3D: A RANDOMIZED PHASE III TRIAL COMPARING SIMPLE UNPLANNED PALLIATIVE RADIOTHERAPY VERSUS 3D CONFORMAL RADIOTHERAPY FOR PATIENTS WITH BONE METASTASES

Principal Investigators: Dr. Robert Olson
BC Cancer – Centre for the North
250-645-7325

Principal Investigators at Additional Participating BC Centres:

Benjamin Mou, MD Radiation Oncology
BC Cancer Agency – Kelowna
Telephone Number: 250-712-3911 Ext 686645

Devin Schellenberg, MD Radiation Oncology
BC Cancer – Surrey
Telephone Number: 604-930-4085

Shilo Lefresne, MD Radiation Oncology
BC Cancer - Vancouver
Telephone Number: 604-877-6000 Ext. 672673

Boris Valev, MD Radiation Oncology
BC Cancer Agency – Victoria
Telephone Number: 250-519-5426

Sponsors: BC Cancer

For emergencies only: Call the centre nearest you and ask for your study doctor or, if he or she is not available, ask for your usual oncologist or the oncologist on-call.

Vancouver	(604) 877-6000
Victoria	(250) 370-8000
Surrey	(604) 581-2211
Abbotsford	(604) 851-4700
Kelowna	(250) 862-4000
Prince George	(250) 645-7300

For non-emergency contact numbers: See sections 19 and 20

1. Invitation

You are being invited to take part in this research study because your cancer has spread to the bone and you will receive radiotherapy (RT) as treatment for your symptoms related to the bone metastases.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant you and your doctor also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

This study is being conducted by the Department of Radiation Oncology at BC Cancer. This study is not receiving funds from an external agency or sponsor.

4. Background

Bone metastases are the most common site of distant metastases and can cause severe symptoms. These complications can greatly affect a patient's quality of life and cause a significant amount of pain. Radiotherapy (RT) is an effective treatment for patients with painful bone metastases. SUPR (simple unplanned Palliative Radiotherapy) is currently the standard treatment technique for bone metastases in BC.

In radiotherapy, multiple techniques can be used. Examples of these are Simple Unplanned Palliative Radiotherapy (SUPR) and Volumetric Modulated Arc Therapy (VMAT). SUPR is the standard of care in BC. For the SUPR treatment technique, simple calculations are performed for the radiation plan and the radiation is delivered with simple radiation beams. The advantage of this, is a quick turn-over which means that patients can be treated (or start treatment) within 24 hours, while the downside is that nearby normal tissue is not spared from radiotherapy. Conversely, with VMAT, a form of 3-dimensional radiotherapy, more complex calculations are done in order to spare nearby normal tissue, and patients typically need to wait 1-3 days before treatment can be started.

This study will allow us to determine if there is reduced toxicity associated with VMAT compared to SUPR while also measuring the impact on resources.

This study will enroll 250 participants. Approximately 150 people will take part from BC Cancer.

5. What is the purpose of the study?

The primary purpose of this study is to compare patient reported quality of life related to nausea and vomiting (RINV) between standard palliative radiotherapy and VMAT and to further explore any benefits in terms of toxicity associated with VMAT compared to SUPR. Additionally, we will evaluate the rate of complete control of RINV, toxicity, and pain response.

6. Who can participate in this study?

You may be able to participate in this study if*:*

- You are 18 or older.
- You provide written informed consent.
- You have a diagnosis of cancer with bone metastases.
- You are going to receive palliative intent radiation therapy (RT).
- Your Radiation Oncologist believes it is safe to treat you with SUPR.
- You are able to do light activities.
- Your Radiation Oncologist believes you are healthy enough to participate in this study.
- You are able and willing to complete the questionnaires, and other assessments that are a part of this study using PatientPortals.ca or REDCap and therefore agree to providing your email address.
- You will be required to be on an anti-nausea medication for treatment.

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You have other serious medical issues that could affect your ability to participate.
- There is evidence of spinal cord compression.
- You are a pregnant or breastfeeding.
- You require treatments outside standard clinical hours.
- You have had whole brain RT within 4 weeks of your bone metastases RT.
- You have an implanted electronic device within 10 cm of the RT fields.
- You have prostheses close to the radiation target area.
- You have had previous RT that requires an analysis of cumulative dosages.

8. What does the study involve?

If you agree to participate in the study, you will receive one of the two radiation treatments listed below. The process for assigning which treatment you will have is random (like flipping a coin) with equal chance of getting either treatment. Neither you nor your study doctor can choose which treatment you will get but it will be assigned in a random way by a computer.

1. Simple unplanned Palliative Radiotherapy (SUPR): This is standard of care palliative radiotherapy in BC. You require a CT scan to plan the radiotherapy, which usually takes 1 hour, and then usually you can receive radiotherapy within 24 hours. The treatment time is usually under 30 minutes.
2. Volumetric Modulated Arc Therapy (VMAT): Like standard of care SUPR, you will require a 1 hour CT scan to plan radiotherapy. The treatment is also usually on 30 minutes. The main

difference you will notice is that the planning time would be up to 3 days; the extra time required is one of the items we are studying.

9. What are my responsibilities?

If you agree to participate in the study, you will be expected to undergo the treatment assigned by the randomization process. We also expect that you will complete the questionnaires required for the study.

If you are unable to return to the clinic 5 days (if applicable), 2 weeks, and 4 weeks post treatment you will need to complete the questionnaires online using the PatientPortals.ca or REDCap system. BC Cancer is licensed by PatientPortals.ca and REDCap to collect data. Patient registration and use of PatientPortals.ca and REDCap is free of charge.

10. What are the possible harms and discomforts?

In VMAT, the bone metastasis will be contoured (outlined) on the CT images and the radiation dose will be planned closely surrounding these contours. Therefore, there is a small theoretical risk of missing part of the metastasis, if this is not visible on CT or other imaging modalities. In SUPR, larger fields are being used, which results in a larger margin surrounding the metastasis. This reduces the risk of missing cancer cells.

We do not anticipate any additional harms or discomforts from participating in this study. There is a possibility due to increased planning time required there may be a slight delay in receiving treatment of 1 to 3 days. This delay in radiation may mean a delay in you receiving pain relief if you take part in this study.

11. What are the potential benefits of participating?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

12. What are the alternatives to the study treatment?

If you choose not to participate in this study or to withdraw at a later date, the following treatment options may be available to you:

- SUPR (simple unplanned Palliative Radiotherapy) would still be made available to you. This is currently the standard treatment technique for bone metastases in BC.

You can discuss these options with your doctor before deciding whether or not to participate in this research project.

13. What if new information becomes available that may affect my decision to participate?

If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

14. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data If you would like to request the withdrawal of your data, please let your study doctor know.

15. Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about the treatment, your research doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

16. Privacy and Confidentiality

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the study is referred to as the 'study-related data'. This data may include your medical records, biological materials, genetic information, completed questionnaires and/or diaries, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer unless otherwise specified in this form (this is referred to as 'coded data').
- Coded data (including genetic information) from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these

future studies is to benefit people by improving our understanding of health conditions like cancer.

Who will know I participated?

- Your family doctor will be notified that you are taking part in this study so that your study doctor and family doctor can provide the proper medical care.
- If required by law, your medical information may also need to be given out. If this should happen, the study doctors and staff will do their best to make sure that any information that is shared will not directly identify you.

A description of this clinical trial will be available on http://www.clinicaltrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHO WILL HAVE ACCESS TO YOUR STUDY-RELATED DATA?

Your signed consent form will be included in your study-related data, and in any electronic medical record(s). Your healthcare team will also be alerted that you are on a study to ensure they can treat you safely according to the study protocol.

Your study-related data will be reviewed by the sponsor of this study, or their representatives at BC Cancer. The BC Cancer Research Ethics Board or regulatory authorities and auditors may also look at your study-related data for the purpose of overseeing the conduct of the study. These reviews may be conducted on site or remotely which requires sharing the study-related data electronically through a secure process. All study-related data is treated confidentially and all efforts are made to restrict access and to transfer your study-related data as securely as possible. Only essential study-related data is shared and is coded with your study code. However, there may be times when identifiable information may also be shared but access to this information will be restricted only to authorized personnel.

Table 2 sets out the organizations that may access your study-related data and for what purposes. By signing this form, you are authorizing such access.

Table 2: Access to your study-related data

WHO	WHAT	WHERE	PURPOSE
Study Monitors	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial, review of data accuracy
Auditors	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial, review of trial conduct
BC Cancer REB	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial

Use of Patientportals.ca or REDCap

Although you may not be aware of this fact, emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States). Due to the fact that

future emails contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue. If you choose not to consent, you will not be able to access PatientPortals.ca or REDCap. Providing your email means that you voluntarily agree and give your consent for BC Cancer to use your personal email. If you agree to use this service, you can provide your email address on the signature page of this consent form.

17. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

18. What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

Reimbursement
You will not be reimbursed for study-related expenses such as specify, e.g., parking, etc.

Remuneration
You will not be paid for participating in this study.

19. Who do I contact if I have questions about the study during my participation?

If you have questions about taking part in this study or if you suffer a research-related injury you can talk to your study doctor, or family doctor. If you suffer a study-related injury you should immediately talk to your study doctor, or if he or she is not available the oncologist on call. Your study doctor is:

_____	_____
Name	Telephone

Or, you can speak to the doctor who is the BC Cancer principal investigator, Dr. Rob Olson, at 250-645-7325.
Or, you can speak to the Head of the Radiation Therapy Program of BC Cancer at 604-877-6000.

20. Who do I contact if I have any questions or concerns about my rights as a participant?
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number H18-01938 when contacting the Complaint Line so the staff can better assist you

21. Signatures

SUPR-3D: A RANDOMIZED PHASE III TRIAL COMPARING SIMPLE UNPLANNED PALLIATIVE RADIOTHERAPY VERSUS 3D CONFORMAL RADIOTHERAPY FOR PATIENTS WITH BONE METASTASES

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I understand I need to provide my email address in order to complete the questionnaires online using the PatientPortals.ca or REDCap system: _____

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____

Participant's Signature Printed Name Date

_____

Signature of Person Obtaining Consent | Printed Name | Study Role | Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

☐ Yes ☐ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check "no".]

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed Name	Date